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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,718	11/21/2001	James X. Hartmann	6818-26	3915

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EXAMINER	
NGUYEN, BAO THUY L	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 07/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/990,718	HARTMANN ET AL.	
	Examiner	Art Unit	
	Bao-Thuy L. Nguyen	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 10-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 10-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed 5/24/2004 has been received. Claims 1-7 and 10-22 are pending.

2. All rejections not reiterated herein below are withdrawn.

3. The text of those US codes not found in this office action may be found in a previous office.

Claim Rejections - 35 USC § 103

4. Claims 1-7 and 10-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rossi et al., (Hybridoma. Vol. 11, No. 3. 1992, pp. 333-338) in view of May (GB 2,204,398) for reasons of record which are reiterated herein below.

Rossi discloses a field-portable immunoassay kits for sailfish using a monoclonal antibody conjugated to an enzyme label. Rossi suggests that adaptation of the assay to a paper format would further reduce the assay thus offering additional advantages to field test. See page 335-337.

Rossi differs from the instant invention in failing to teach a lateral flow assay device using nitrocellulose and various reagents that are conventional in a lateral flow assay device such as gold sol label.

May, however, teaches a kit comprising an assay device made of a hollow casing constructed of moisture-impervious solid material containing a dry porous carrier which communicates directly or indirectly with the exterior of the casing such that a liquid test sample can be applied to the porous carrier, the device containing a labeled specific binding reagent for an analyte which labeled specific binding reagent is freely mobile within the porous carrier when in the moist state, and unlabeled specific binding reagent for the same analyte which

unlabeled reagent is permanently immobilized in a detection zone on the carrier material (page 3). The device contains a control zone is loaded with an antibody that will bind to the labeled antibody from the first zone. The control zone can contain an anhydrous reagent that when moistened, produces a color change or color formation. Or as an alternative, the control zone could contain immobilized analyte that will react with excess labeled reagents from the first zone (page 9). May teaches the use of direct labels such as minute colored particles, such as dye sols, metallic sols and colored latex particles (page 10). The metallic sols particles are in the range of about 20 nm in diameter (page 31).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to adapt the assay taught by Rossi to a paper lateral flow format such as taught by May because Rossi teaches that such adaptation would reduce the assay time and therefore increase productivity. Furthermore, May teaches that their device may be adapted for a variety of analytes and provides the advantages of a device suitable for use in the field that can provide analytical result that is rapid and requires a minimum degree of skill and involvement from the user leading to fewer errors.

Response to Arguments

5. Applicant's arguments filed 5/24/2004 have been fully considered but they are not persuasive.

Applicant argues that Rossi is an irrelevant prior art reference as it fails to teach or suggests a lateral flow immunoassay device, and May discloses a two-zone detection assay requiring the use of two antibodies. As argued by Applicant, such a device must contain the appropriate antibodies for the appropriate test and does not offer flexibility in field condition.

In contrast, Applicant argues that the instant invention involves a lateral flow test device where a test sample is immobilized and thus such a device is ready for use under any conditions for any sample is not limited in specificity.

These arguments have been fully considered but are not persuasive. Even though the instant claims recite a lateral flow immunoassay, such recitation is in the preamble, and because no other limitation of a "lateral flow" device is recited in the body claim, this is not a positive limitation of the claim.

Claim 1, as written, requires a substrate having an immobilized billfish specific antigen-containing sample. If this claim is broadly interpreted, this limitation is taught by Rossi at page 335, *Assay of Billfish sera.*

Claim 2 requires that the substrate be nitrocellulose. See May, page 5, lines 10-25.

Claim 3 requires that the nitrocellulose substrate be backed by plastic. See May, page 13, lines 33-36.

Claim 4 requires that the substrate of claim 1 has two ends, the first end has an immobilized billfish-specific antigen containing sample, and a second send. The recitation that this second end is adapted to receive a solution is irrelevant, since any nitrocellulose substrate can inherently be adapted to receive a solution. Therefore, May meets this limitation. The solution comprising an antibody specific to the billfish specific antigen is not a positive limitation of the test device, since it is not recited as being part of the device.

Claim 5 requires that the solution, in addition to comprising an antibody specific for the billfish antigen, further comprises a portion of the test sample. This claim does not add to the device of claim 1 because the solution, as explained above, is not part of the device.

Claims 6 and 7 require that the billfish antigen is sailfish serum albumin. See Rossi, pages 335 and 336.

Claims 10-14 recite steps of using the device and thus are not considered positive limitation of the device.

Claim 15 requires a non-billfish specific antigen immobilized on the substrate. See Rossi, page 335 where bovine serum albumin was used as standards. Furthermore, May teaches the use of a control zone comprising non-analyte reagent immobilized on the substrate.

Claim 16 is directly to a test kit comprising a substrate similar to the substrate of claim 1, and a solution comprising an antibody that binds the billfish specific antigen. Rossi discloses such a solution at pages 335 and 336.

Claims 17 and 18 requires that the billfish specific antigen be serum albumin from sailfish, blue marlin and white marlin. See Rossi, page 335, *Assay of Billfish sera.*

Claims 19-21 requires that the antibody be labeled with gold sol particles having diameter between 10-40 nm. See May, page 5, lines 26-36.

Claim 22 requires non-billfish specific antigen immobilized on the substrate. Again, see Rossi, page 335 where bovine serum albumin was used as standards. Furthermore, May teaches the use of a control zone comprising non-analyte reagent immobilized on the substrate.

Because Rossi teaches the immobilized of billfish specific antigen to a substrate, and further teaches labeled antibodies specifically binding to these antigens, and because May teaches a lateral flow assay format, as well test kits comprising appropriate reagents, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the assay device taught by May to includes reagents for a billfish assay because May teaches that their device may be adapted for a variety of analytes and provides the advantages

of a device suitable for use in the field that can provide analytical result that is rapid and requires a minimum degree of skill and involvement from the user leading to fewer errors.

Applicant argues that the instant device differs from that of May because it claims the immobilization of a test sample, as such any sample can be immobilized requiring the addition of one desired antibody for detection. Thus, applicant's device is ready for use under any conditions for any sample and is not limited in specificity by devices already containing immobilized antibodies where the device is useful for only predesignated test. This argument has been fully considered but is not persuasive. First, it is confusing to claim a device where a test sample is already immobilized thereon, because test samples are normally not obtained or available until the time of the assay, therefore, a ready made device having an immobilized test sample is confusing; however, it is applicant' pejorative to define and claim their invention. Second, the argument that applicant's device is ready for use under any conditions for any sample and is not limited by specificity is confusing since Applicant's device **is**, in fact, limited by specificity. The instant device cannot be used with **any sample** as claimed, but is limited to samples containing billfish specific antigen. Furthermore, the instant antibody must be specific for the billfish antigen in order for the device to function as claimed, i.e. identify the presence of tissue from a species of billfish in a test sample. Therefore, the argument that the instant device is ready for use under any conditions for any sample is not persuasive.

The argument that May does not teach a device where the sample is immobilized and a billfish specific antibody is added for detection of antigen is not persuasive. May teaches a device where an analyte, such as the sailfish albumin taught by Rossi, can be captured via an immobilized antibody (i.e. immobilization of a test sample) and detected via a gold sol labeled

antibody specific for the analyte. The recitation of adding billfish specific antibody is not a positive limitation of the claimed device, therefore, it is not given patentable weight.

Applicant argues that because May does not teach the production of antibodies that would detect billfish specific antigen, it would require undue experimentation for one of ordinary skill in the art to make and use such a device. This argument is not persuasive. May is cited for their teaching of a lateral flow device comprising immobilized analyte, such as billfish specific antigen, and Rossi is cited for their teaching of billfish antigens, monoclonal antibodies specific therefor, and the desirability of assays for detect different species of billfish. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in adapting the assay taught by Rossi to a lateral flow format such as taught by May.

The argument regarding the gold sol labeling of billfish specific antibodies is not persuasive. Clearly, labeling of antibodies with gold sol particle is not a novel procedure. May specifically teaches that labels such as enzymes, gold sol and latex particles are functionally equivalent. In addition, May teaches that the use of direct labels such as gold sol offer the advantage of direct observation of a test results. Therefore, a skilled artisan would have had a reasonable expectation of success and would have been motivated to substitute the enzyme labels taught by Rossi with the direct labels taught by May for the advantages discussed therein.

Conclusion

6. No claim is allowed.

7. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 9:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BAO-THUY L. NGUYEN
PRIMARY EXAMINER
7/27/04